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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------|------------------------|
| 10/539,720 | 07/18/2005 | David John Pritchard | ABL-011.5P US | 6344 |
| 7590 Leon R Yankwich Yankwich & Associates 201 Broadway Cambridge, MA 02139 | | | | |
| | | | EXAMINER COOK, LISA V | |
| | | | ART UNIT 1641 | PAPER NUMBER |
| | | | MAIL DATE 10/16/2009 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,720

Applicant(s)

PRITCHARD, DAVID JOHN

Examiner

LISA V. COOK

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 57-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-13,17,22,26-28,30,33-39,43,44,52,70,75,77,79-83,88,90 and 91.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-13,17,22,26-28,30,33-39,43,44,52,57-70,75,77,79-83,88,90 and 91.

DETAILED ACTION

Amendment Entry

1. Applicant's response and amendment filed 6/15/09 is acknowledged. In the amendment filed therein claims 1, 57, 59, 60, 61, 62, 63, and 66 have been modified.
2. Claims 2-13, 17, 22, 26-28, 30, 33-39, 43-44, 52, 70, 75, 77, 79-83, 88, and 90-91 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/28/08. Currently claims 1 and 57-69 are under consideration.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- I. Claims 1, 57, 58, 59, 60, 61, 62, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Michael Esnouf (U.S. Patent #5,500,349).

Esnouf discloses procedures to measure factor β XII or factor β XIIa via antibodies that show no substantial binding to factor XII. Esnouf utilizes the same antibodies that are disclosed by the instant specification for differential factor XIIa detections (antibodies 2/215, 201/9, 202/16.1.9). For example, see page 13 of the disclosure.

The detected factor XIIa is taught to be useful in various diseases or disorders. The diseases include heart diseases like ischemic heart disease and acute myocardial infarction (AMI). See column 2 lines 40-46. The detected factors are utilized in studying blood coagulation systems and thrombotic disorders. See abstract and column 11 through column 12. Methods of comparing the measured results to controls are also discussed. See column 4 lines 1-11.

Response to Arguments

Applicant contends that the patent to Esnouf does not anticipate the instant invention because it is silent with respect to the type of factor XIIa that is measured. In particular, Applicant argues that Esnouf does not teach *celluar* factor XIIa. This argument was carefully considered but not found persuasive because the characteristic of "celluar" necessarily flows from the teachings of the applied prior art. See MPEP 2112 [R-3]. The cited patent teaches the measurement of factor XIIa in disease. It employs the same antibodies taught by the instant disclosure, it necessarily flows that the same antibodies would measure factor XIIa regardless of its presence in the cell (cellular, intracellular, etc). Even though every limitation is not disclosed in the prior art reference, anticipation can be found on the inferences which one skilled in the art would reasonably expect to draw therefrom. *In re Preda* (CCPA 1968) 401 F2d 825, 159 USPQ 342.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

II. Claims 64-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael Esnouf (U.S. Patent #5,500,349) in view of Coppola et al. (Blood Coagulation & Fibrinolysis, 1996, Vol. 7, No.5, pages 530-535, Abstract Only).

Please see Michael Esnouf as set forth above.

Michael Esnouf differs from the instant invention in not specifically teaching the measurement of factor XIIa in sepsis and disease treatment.

However, Coppola et al. teach procedures for utilizing factor XIIa in sepsis detection and treatment with thrombolytic agents. FXIIa was significantly higher in patients with severe sepsis. The use of the immunoassay of FXIIa permitted a more direct study of the contact phase of blood coagulation in situations in which the coagulation system may play a pathophysiological role. See abstract.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ FXIIa measurements in sepsis and disease treatments as taught by Coppola et al. in the Factor XIIa detection procedure of Esnouf because Coppola et al. taught that the use of the immunoassay of FXIIa permitted a more direct study of the contact phase of blood coagulation in situations in which the coagulation system may play a pathophysiological role. See abstract.

Response to Arguments

Applicant contends that Coppola et al. do not cure the deficiency of Esnouf. Esnouf has been addressed a priori and maintained. Accordingly the rejection including Coppola et al. is maintained.

5. For reasons aforementioned, no claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Lisa V. Cook,
Remsen
(571) 272-0816
10/13/09*

/Lisa V. Cook/
Primary Examiner, Art Unit 1641